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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/467,928	12/21/1999	DAVID GAILLAC	017753-120	2965

21839 7590 01/28/2003

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EXAMINER

PARKIN, JEFFREY S

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 01/28/2003

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/467,928

Applicant(s)

GAILLAC ET AL.

Examiner

Jeffrey S. Parkin, Ph.D.

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 03 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 October 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 13-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Response to Amendment

Status of the Claims

1. Acknowledgement is hereby made of receipt and entry of the amendment submitted 30 October, 2002, wherein claim 1 was amended. This application contains claims 13-15 drawn to an invention non-elected with traverse. A complete response to the final rejection must include cancellation of non-elected claims or other appropriate action (refer to 37 C.F.R. § 1.144 and M.P.E.P. § 821.01). Claims 1-12 are currently under examination.

35 U.S.C. § 112, Second Paragraph

2. Claims 1-12 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims remain vague and indefinite for reciting claim limitations employing the term "about". Contrary to applicants' assertion, the phrase fails to clearly set forth the metes and bounds of the patent protection desired. For instance, claim 1 contains the phrases "about -5°C and +50°C" and "about 5 and about 9", which are vague and indefinite since the precise parameters of the claimed invention are not readily manifest. Appropriate correction is still required.

35 U.S.C. § 103(a)

3. The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner

in which the invention was made.

5 Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

10 4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of
15 the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103© and potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).

20 5. The previous rejection of claims 1-12 under 35 U.S.C. § 103(a) as being unpatentable over Kameyama *et al.* (1990), is hereby withdrawn in response to applicants' amendment.

25 6. Claims 1-12 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Kameyama *et al.* (1990) in view of Gao and Wilson (2001). Kameyama and colleagues disclose methods for the inactivation of enveloped viruses that are contaminating a protein-containing composition by treating said compositions with 0.3%
30 (w/v) TNBP and 1% (w/v) Tween 80 (see Examples 1 and 2, pp. 7 and 9, respectively). This procedure resulted in the inactivation of various enveloped viruses (e.g., VSV or Sindbis virus) without adversely affecting the infectivity of a non-enveloped virus (e.g., Echo virus). Various routine experimental parameters are also
35 described (e.g., % of TNBP, % of detergent, temperature ranges, conductivity ranges, pH ranges, etc.). Gao and Wilson (2001)

disclose the medical importance of adenoviral vectors and their use in therapeutic compositions.

While Kameyama et al. (1990) do not disclose the inactivation of enveloped viruses in an adenoviral-containing preparation, nevertheless, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to subject viral preparations comprising both enveloped viruses and non-enveloped adenoviruses to the aforementioned treatments, since this would provide a means of ensuring the safety of non-enveloped adenoviral vector preparations for any one of a number of purposes such as gene therapy or diagnostic applications. Moreover, Kameyama et al. (1990) state (p. 3, l. 13-25) that "There is no particular limitation posed on the protein-containing liquid composition to which the method of the present invention is applied. Examples thereof include plasma or tissue extracts, solutions comprising a fraction obtained by treating plasma or tissue extract by various fractionation methods, culture broths obtained by culturing a gene recombinant host or tissue and commercially available protein preparations (in a liquid form) or their solutions." Thus, both the motivation and a reasonable expectation of success were present in the prior art.

Finality of Office Action

7. Applicant's amendment necessitated any and all new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL.** See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a). **A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED**

STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS
MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL
BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO
EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX
5 MONTHS FROM THE DATE OF THIS FINAL ACTION.

Correspondence

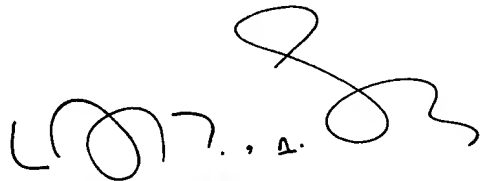
10 8. Correspondence related to this application may be submitted to
Group 1600 by facsimile transmission. The faxing of such papers
must conform with the notice published in the Official Gazette,
1096 OG 30 (November 15, 1989). Official communications should be
directed toward one of the following Group 1600 fax numbers: (703)
308-4242 or (703) 305-3014. Informal communications may be
15 submitted directly to the Examiner through the following fax
number: (703) 308-4426. Applicants are encouraged to notify the
Examiner prior to the submission of such documents to facilitate
their expeditious processing and entry.

20 9. Any inquiry concerning this communication should be directed to
Jeffrey S. Parkin, Ph.D., whose telephone number is (703) 308-2227.
The examiner can normally be reached Monday through Thursday from
8:30 AM to 6:00 PM. A message may be left on the examiner's voice
mail service. If attempts to reach the examiner are unsuccessful,
25 the examiner's supervisors, James Housel or Laurie Scheiner, can be
reached at (703) 308-4027 or (703) 308-1122, respectively. Any
inquiry of a general nature or relating to the status of this
application should be directed to the Group 1600 receptionist whose
telephone number is (703) 308-0196.

Respectfully,

Jeffrey S. Parkin, Ph.D.
Patent Examiner
Art Unit 1648

24 January, 2003


LAURIE SCHEINER
PATENT EXAMINER